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October 7, 2005

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: **Docket No. 2004P-0074**
Comments to Citizen Petition Filed on Behalf of
Savient Pharmaceuticals, Inc.

Dear Sir or Madam:

These comments to the February 25, 2005 supplement (Supplement 3) to the Citizen Petition (the Savient Petition) filed by Savient Pharmaceuticals, Inc. (Savient) on February 16, 2004 are respectfully submitted under 21 C.F.R. § 10.30(d).

The Savient Petition requests that the Food and Drug Administration (FDA) establish specific bioequivalence requirements for oral products containing oxandrolone. As demonstrated by our September 27, 2004 comments, there is no scientific or legal basis for FDA to take such action. Perhaps recognizing the weakness of its earlier arguments, Savient now requests in Supplement 3 that FDA apply unvetted impurity standards to drug substances used in oxandrolone drug products. As with Savient's original petition, this request is not supported by any credible information.

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The Pharmacopeial Forum (PF), a bimonthly publication of the United States Pharmacopeia (USP), provides a forum for review and comment of new or revised USP standards, through the publication of “in-process revisions.” Volume 31 of the PF includes an in-process revision to the USP’s oxandrolone monograph. That revision, if adopted, would replace the liquid chromatographic procedure in the test for related compounds with a linear gradient elution method. Despite the draft nature of this proposed revision, Savient’s Supplement 3 requests that FDA require any oxandrolone ANDA applicant to comply with it.

Supplement 3 fails to recognize, or even acknowledge, the value of public review and comment, and the real potential that this process will result in changes to the proposed revision prior to its finalization. Public comment may also result in a decision to entirely abandon the proposed method. That an in-process revision may not be ultimately published in the USP is clear when considering the history of the oxandrolone monograph itself. A previous in-process revision to the test for related compounds was published in PF 30(1) [Jan.-Feb. 2004] and was abandoned after the comment period in favor of this new revision – the fate of which could be the same. Ignoring the draft nature of the revision, Supplement 3 makes repeated reference to the requirement that a compendial drug comply with compendial standards, incorrectly implying that the current in-process revision is a part of a finalized monograph. Instead of recognizing the procedural realities of the PF process, Supplement 3 focuses on the merits of the in-process revision – an issue more appropriately debated through the USP’s PF public comment process.¹

In summary, failure to comply with a proposed revision to a USP drug substance monograph cannot delay the approval of oxandrolone ANDAs. As with the original Savient Petition, we request that FDA deny the actions requested in Supplement 3 because they are not supported by the law.

¹ We note that substantial debate on the merits of the revision is likely to occur. For instance, the lack of USP reference standards for any of the related compounds listed in the monograph is highly problematic. A requirement that ANDA applicants meet the acceptance criteria in the in-process revision would mean that only those parties with access to the reference standards could release API for tablet manufacture. In apparent recognition of this problem, the USP itself notes that “[s]tandards, tests, or assays in new monographs requiring USP reference standards are not official until the reference standards become available.” These and other substantive issues are likely to be submitted to USP as comments on the proposed revision.

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We appreciate the opportunity to submit these comments and look forward to FDA action on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert A. Dormer". The signature is fluid and cursive, with the first name "Robert" being more prominent.

Robert A. Dormer

RAD/dh